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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company),

Plaintiffs,

v.

DEREK BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF UTAH,

and

JON PIKE, in his official capacity as INSURANCE COMMISSIONER OF THE STATE OF UTAH,

Defendants.

PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Case No. 2:25-cv-00271

Judge David Barlow
Magistrate Judge Daphne A. Oberg

HEARING REQUESTED

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Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Pharmacyclics LLC, Allergan Sales, LLC (collectively "AbbVie" or "Plaintiffs"), hereby submit the following Motion for a Preliminary Injunction.

PRECISE RELIEF SOUGHT AND GROUNDS FOR MOTION

AbbVie respectfully requests that, during the pendency of the remainder of this case, the Court enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, enjoining the Utah Insurance Commissioner and Attorney General, and all those acting in concert with them, from enforcing S.B. 69. The grounds for this relief are as follows:

1. AbbVie is likely to succeed on the merits of its claims that S.B. 69 is unconstitutional under the Supremacy Clause, Takings Clause, and Due Process Clause of the U.S. Constitution;
2. AbbVie will be irreparably harmed by enforcement of the law;
3. The balance of equities weighs heavily in AbbVie's favor; and
4. A preliminary injunction serves the public interest by preventing the enforcement of an unconstitutional state law.

INTRODUCTION

AbbVie seeks to preliminarily enjoin S.B. 69, Utah's unconstitutional attempt to modify the federal 340B program.[1] S.B. 69 expands the categories of eligible "340B entities" to include commercial contract pharmacies, and compels drug manufacturers to transfer their drugs—not

[1] AbbVie has raised four claims for relief in its underlying complaint. AbbVie alleges violations of the Supremacy Clause, Compl. ¶¶ 120–133 (citing U.S. Const. art. VI, cl. 2); the Takings Clause, *id.* ¶¶ 134–144 (citing U.S. Const. amends. V, XIV); the Due Process Clause, *id.* ¶¶ 145–153 (citing U.S. Const. art. XIV); and the Commerce Clause, as interpreted by Supreme Court precedent applying the dormant Commerce Clause doctrine, *id.* ¶¶ 154–164 (citing U.S. Const. art. 1 § 8).

only to the covered entities identified by Congress—but to an unlimited number of "locations" "authorized" by both covered entities ***and*** commercial pharmacies. The Utah law imposes obligations that appear nowhere in the federal 340B statute, changes the terms of participation in a federal program, and forces a private transfer of property to for-profit actors. S.B. 69 also prohibits manufacturers' "interfer[ence] with . . . a contract between a pharmacy and a 340B entity." S.B. 69 § 1(2)(c)(i). Setting aside that Utah law defines "340B entity" to itself include pharmacies—arguably covering contracts between and among pharmacies (not covered entities) and other unidentified third parties—manufacturers have no idea ***what*** those contracts say, as covered entities and contract pharmacies zealously guard those terms as proprietary and trade secrets. UTAH CODE ANN. § 34A-46-102(3)(c). Nor does the statute contain any scienter requirement. Manufacturers have no idea what terms they could arguably "interfere" with, and could do so even by accident. S.B. 69 deprives manufacturers of sufficient notice to circumscribe their conduct in accordance with the law. S.B. 69 violates the Supremacy, Takings, and Due Process clauses of the U.S. Constitution and should be enjoined.

In 1992, Congress created the 340B drug program which requires drug manufacturers—as a condition of participation in federal Medicare and Medicaid—to ***offer*** certain drugs, at discounted prices, to specified non-profit entities referred to as "covered entities." *See Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011); Ex. 1, Ex. A (Pharmaceutical Pricing Agreement). In recent decades, however, covered entities have sought to share their statutory right to access heavily discounted drugs with for-profit commercial pharmacies. What happens is this: A covered entity agrees to allow a commercial pharmacy, such as CVS or Walgreens, to serve as its "contract pharmacy" for dispensing 340B-discounted drugs; the pharmacy then obtains the drugs from manufacturers at below market prices (often for pennies), sells the drugs to patients at

full market price, and splits the windfall profit with the covered entity. Congress deliberately designed the 340B program to require only an "offer" of discounted drugs to covered entities—not sales, and certainly not sales under state-mandated terms. *See* 42 U.S.C. § 256b(a)(1).

As the Third and D.C. Circuits have recognized, the 340B statute does ***not*** require manufacturers to deliver drugs at 340B-discounted prices to an unlimited number of contract pharmacies and it leaves manufacturers discretion to structure their own transactions. *See Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 707 (3d Cir. 2023); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 464 (D.C. Cir. 2024). Congress did not give contract pharmacies a right to benefit from the federal program and access drugs at 340B-discounted prices. The district court in *PhRMA v. Morrisey* agreed, enjoining a nearly identical state law, and concluding that laws like S.B. 69 regulate "price, not delivery," and manufacturers risk violating such laws "not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering [their] drugs to those pharmacies." --- F. Supp. 3d ---, 2024 WL 5147643, at *8–9 (S.D. W. Va. Dec. 17, 2024). Nor does a manufacturer's voluntary participation in Medicare and Medicaid entitle a state to demand discounted drug sales—particularly when Congress itself does not even mandate sales, but merely requires manufacturers to ***offer*** discounted drug pricing to a defined list of fifteen covered entity types. As the Chief Judge of the United States Court of Appeals for the Fifth Circuit recently recognized, states cannot compel manufacturers to sell at a particular price under the pretense of furthering Congress's purpose. *See AbbVie et al. v. Fitch*, No. 24-60375 (5th Cir. oral argument Apr. 2, 2025) at 23:00.36–23:23.28 ("*Fitch* Oral Argument") (explaining AbbVie agreed to sell its drugs "in the program that they

signed up through Congress with," but asking "they didn't ever agree with Mississippi to sell them the product at this rate . . . where did they do that?").[2]

Utah's S.B. 69 expressly attempts to change the requirements of federal law—and hence the conditions of participation in Medicare and Medicaid—by mandating that manufacturers provide ***drugs discounted under that federal program*** to an unlimited number of contract pharmacies (and virtually any third-party) on demand. That is unconstitutional. As relevant, S.B. 69 is preempted because it intrudes upon a field occupied exclusively by the federal 340B program and conflicts with Congress's goals and objectives. S.B. 69 effects an unconstitutional taking because it requires drug manufacturers to give their property to other private parties, for pennies on the dollar, and not for any recognized public use. And finally, S.B. 69 runs afoul of the Due Process clause by failing to provide manufacturers notice of how they may possibly "interfere" with contracts between covered entities and contract pharmacies—because manufacturers have no clue what those contracts say.

Faced with competing obligations under the 340B program and the possibility of criminal sanctions for noncompliance, AbbVie seeks preliminary injunctive relief. AbbVie has demonstrated a strong likelihood of success on the merits of its constitutional challenge to S.B. 69. AbbVie will be irreparably harmed by the immediate taking of its property worked by S.B. 69, a federally preempted statute. The State of Utah would suffer no prejudice from the enjoining of an unconstitutional law, while the public interest favors the preservation of our federal structure and Fifth Amendment rights. A preliminary injunction should issue.

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[2] https://www.ca5.uscourts.gov/OralArgRecordings/24/24-60375_4-2-2025.mp3.

STATEMENT OF FACTS

A. The Origins of Section 340B and Its Design.

In 1992, Congress enacted Section 340B of the federal Public Health Service Act ("340B program"), 42 U.S.C. § 256b *et seq.*, to help uninsured, low-income patients by providing access to prescription medications at deeply discounted prices. The statute limits who can participate, narrowly defining "covered entities" to include only certain enumerated non-profit organizations serving primarily low-income and uninsured patients. No for-profit entity appears on Congress's list. 42 U.S.C. § 256b(a)(4).

To participate in the federal Medicaid and Medicare Part B programs, which account for nearly half of the Nation's drug market, manufacturers must sign a Pharmaceutical Pricing Agreement ("PPA"), with the United States Department of Health and Human Services ("HHS"). The PPA is a non-negotiable, statutorily mandated contract incorporating the manufacturer's obligation to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). The statute's pricing formula establishes the "ceiling price" for covered drugs, yielding discounts ranging from 23.1% to more than 99.9% below market prices. *Id.* §§ 256b(a)(1), 1396r-8(c).

Congress also limited how covered entities may use 340B-priced drugs. The statute prohibits "diversion"—transferring discounted drugs to anyone who is not a patient—and "duplicate discounts"—claiming both a 340B discount and a Medicaid rebate for the same drug. *Id.* § 256b(a)(5). Congress vested HHS—through authority delegated to the Health Resources and Services Administration ("HRSA")—with exclusive authority to enforce rules and protect the 340B program's integrity through oversight, audits, and a dispute resolution process.

Id. § 256b(d). Failure to comply can result in contract termination, exclusion from Medicaid, or civil penalties. *Id.* §§ 256b(a)(5)(D), (d)(1)(B)(vi), (d)(3).

B. The Rise of "Contract Pharmacies" and Manufacturers' Response.

Originally, the 340B program was designed to apply to covered entities operating an in-house pharmacy. But in 1996, HHS issued non-binding guidance allowing covered entities without in-house pharmacies to contract with a ***single*** outside pharmacy—so long as the covered entity retained title to the drugs. *See* 61 Fed. Reg. 43,549, 43,551, 43,553 (Aug. 23, 1996). That changed dramatically in 2010, when HHS issued new guidance allowing covered entities to contract with an unlimited number of outside pharmacies, even if they already had an in-house pharmacy. 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). Covered entities quickly exploited this shift. Many entered contracts with numerous pharmacies—often located hundreds of miles away—and began using manufacturers' discounted drugs to generate profits instead of using them for the benefit of the covered entities' indigent and uninsured patients.[3]

This arrangement allowed for-profit pharmacies like CVS Pharmacy ("CVS") and Walgreens, Inc. ("Walgreens") to obtain massive amounts of manufacturers' drugs for pennies, sell them at full price, and split the profits with covered entities. The public has not benefited from this arbitrage scheme. Poor patients rarely receive discounted drugs from these pharmacies, which generally charge full price to both patients and their insurers.[4] Meanwhile, the HHS Inspector General reported that contract-pharmacy arrangements greatly increase the risk of diversion, since

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[3] *See* Ex. 2 at 8–9 (2020 Alliance Report on Contract Pharmacy Growth) (finding that the 340B program, originally intended to benefit poor patients through non-profit entities, has become a profit center for commercial enterprises and the largest federal drug program after Medicare Part D—soon to surpass even that).

[4] *See* Ex. 3 at 9 (IQVIA Report on Patient Receipt of Discounts at Contract Pharmacies) (reporting that patients receive discounts at contract pharmacies less than 1.4% of the time).

contract pharmacies cannot verify 340B eligibility in real time and dispense from their general inventory rather than from a segregated stock of 340B-priced drugs.[5] *See* Ex. 7 at 59:20–60:13 (June 6, 2024 Hr'g Tr.); Ex. 8 at 4–5 (Intervenor Defs.' Reply to Mot. for Sum. J., *AbbVie Inc. v. Murrill*).

Between 2010 and 2024, covered entities' use of contract pharmacies increased by more than ***12,000 percent***.[6] In 2009, 340B sales totaled $4.2 billion; by 2023, they reached an estimated $124 billion in gross profits.[7] Tellingly, when manufacturers revised their 340B policies, CVS and Walgreens disclosed the change as a ***material risk to their business*** in their annual reports.[8]

In February 2025, AbbVie announced its current 340B program integrity initiative, which prohibits hospital covered entities from directing that AbbVie's 340B-priced drugs be transferred to contract pharmacies, unless that hospital covered entity does not have an in-house pharmacy, in which case, the covered entity may select one contract pharmacy within 40 miles of that hospital covered entity's HRSA registered parent site while providing limited data for the one contract pharmacy. *See* Ex. 1, Ex. D at 1–2 (Feb. 27, 2025 Ltr. from E. Scheidler to 340B Covered Entities).

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5 *See* Ex. 4 at 1 (2014 HHS OIG Report on Contract Pharmacy Arrangements); *see also* Ex. 5 at 28 (2011 GAO Report on 340B Manufacturer Discounts); Ex. 6 at 35, 43–44 (2018 GAO Report on Oversight and Patient Discounts at Contract Pharmacies) (reporting that 45% of surveyed covered entities did not provide any discount to patients at contract pharmacies, and many of the remaining 55% did so rarely); *id.* at 44 (noting that 66% of diversion findings in HRSA audits involved contract pharmacies).

6 *See* Ex. 9 at 2 (2025 BRG Update on For-Profit Pharmacy Participation in 340B).

7 *See* Ex. 11 at 2 (2024 IQVIA White Paper on 340B Program Growth to $124B).

8 *See* CVS Pharmacy 10-K (2022) at 22, https://tinyurl.com/mpwpre9x (noting that reduction in contract pharmacy arrangements or in manufacturers' participation in the 340B program could materially harm the Company.); Walgreens, Inc. 10-K at 28 (2022), https://tinyurl.com/mu6tfzcu (stating that changes to 340B program or manufacturer policies could significantly reduce profitability)

Federal grantees may place orders for direct delivery to an unlimited number of contract pharmacies as long as the Grantee registers with 340B ESP™—a web-based platform made available to covered entities at no cost—and submit claims data. *Id.* at 2–3. AbbVie continues to offer unlimited 340B-priced drugs to any covered entity that wants to buy them, as the 340B statute requires. *See Sanofi Aventis*, 58 F.4th at 703. Accordingly, AbbVie's policy in no way affects patient access to 340B-discounted drugs.

AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's 340B-discounted drugs to qualifying patients. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative. Ex. 1, Ex. D. at 1–2. But AbbVie will not indiscriminately accept requests to transfer 340B-discounted drugs to an unlimited number of commercial "contract" pharmacies. *Id.*

C. Federal Courts Rule in Favor of Manufacturers.

Although HHS initially recognized that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies,[9] in December 2020, HHS changed its mind and issued a decision—labeled an "Advisory Opinion"—that for the first time purported to require manufacturers to facilitate the transfer of their products to an unlimited number of for-profit commercial pharmacies.[10]

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[9] *See* Ex. 12 (340B Report Article on HRSA Guidance Enforceability).

[10] *See* HHS, Advisory Opinion No. 20-06, Contract Pharmacies Under the 340B Program (Dec. 30, 2020), https://tinyurl.com/2ca6rmnm.

Litigation ensued, and manufacturers prevailed in two Courts of Appeals.[11] In *Sanofi*, the Third Circuit unanimously upheld manufacturer policies limiting the transfer of discounted drugs to commercial pharmacies, emphasizing that Congress intentionally "chose not to" impose certain obligations on manufacturers. *See* 58 F.4th at 704, 707. The 340B statute's text reflects a model of "one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *Id.* at 704. The court held that manufacturers' policies do not prevent covered entities from participating in the 340B program or from entering into contractual relationships with commercial pharmacies. *Id.* at 707. Covered entities "can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy." *Id*. at 703. The D.C. Circuit reached a similar conclusion: The 340B statute "merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount." *Novartis*, 102 F.4th at 460. So long as a manufacturer's policy does not prevent a bona fide offer, it is lawful—even if it limits delivery to a single pharmacy. *Id.* at 463–64.

When several states—including Utah—enacted their own laws trying to mandate what HHS could not, manufacturers challenged those laws too. The Southern District of West Virginia preliminarily enjoined West Virginia's contract pharmacy law, finding it unconstitutionally conflicted with section 340B. *Morrisey*, 2024 WL 5147643, at *7–12. The court held that laws like S.B. 69 regulate "price, not delivery" because "[t]he question is only about what price the pharmacy and the covered entity will pay." *Id.* at *8. The court recognized that laws like S.B. 69 proscribe not a mere failure to deliver but a failure to deliver ***at a particular price***. *See id.* ("the

[11] *See, e.g.*, *Sanofi Aventis U.S. LLC v. U.S. Dept. of Health & Human Servs.*, 58 F.4th 696 (3d Cir. 2023) (addressing cases filed by three manufacturers); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024) (considering cases filed by two manufacturers); *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs., et al.*, No. 21-3405 (7th Cir.) (pending).

system is about delivery ***at a given price***, not delivery *per se*."). Manufacturers risk violating laws like S.B. 69 "not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering [their] drugs to those pharmacies." *Id.* at *9. The court rejected contrary decisions, criticizing the Eighth Circuit's "rather brief rejection of an obstacle preemption argument." *Id.* at *11. The court also discussed the denial of a preliminary injunction by the District Court for the Southern District of Mississippi, faulting it for failing to take account of "*Astra*'s potential impact on a conflict preemption analysis." *Id*.

D. Utah Attempts To Undo The Third Circuit And D.C. Circuit Rulings.

AbbVie challenges S.B. 69, Utah's state law attempt to impose an obligation rejected by both the Third and D.C. Circuits.[12] S.B. 69 impermissibly seeks to impose Utah's own view of the federal 340B program, attempting to change the requirements of manufacturers' compliance with the federal 340B program. By its terms (which cite to the federal statute), S.B. 69 could not exist absent the 340B program as it defines "340B drug discount program," "340B drug," and "340B entity" by referencing the federal statute. *See* UTAH CODE ANN. §§ 31A-46-102(1)–(3) (referencing 42 U.S.C. § 256b). S.B. 69 directly eliminates manufacturers' ability to either place conditions on their federal offers, as Congress intended, or prevent the taking of their own property by entities not otherwise entitled to it. Additionally, Utah's law expands the pool of entities entitled to receive 340B discounts by expressly defining a "340B entity" to include a commercial contract pharmacy. *Id.* § 31A-46-102(3)(c).

[12] Utah's Attorney General filed amicus briefs on behalf of HHS in both cases, expressing her disapproval of the manufacturers' policies. *See* May 23, 2022 Br., *Novartis Pharmaceuticals Corp. v. Johnson et al.*, No. 21-5299 (D.C. Cir.); ECF No. 34, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.,* 21-3167 (3d Cir.).

S.B. 69 amends Utah's Insurance Code, UTAH CODE ANN. § 31A-1-101 *et seq.*, and thus subjects entities who violate its terms to the enforcement provisions of that Code. UTAH CODE ANN. § 31A-46-401. The Utah Insurance Commissioner is tasked with enforcing the Insurance Code and is statutorily obligated to "issue prohibitory, mandatory, and other orders as necessary to secure compliance with" the Code. UTAH CODE ANN. § 31A-2-201(4)(a). If a manufacturer violates any such order or "any insurance statute"—such as S.B. 69—it must "forfeit to the state up to twice the amount of any profit gained from the violation, in addition to any other forfeiture or penalty imposed." UTAH CODE ANN. § 31A-2-308(1)(a). The Commissioner may also seek an injunction or file suit to enforce any orders and impose "forfeiture[s]" of "up to $10,000 for each day the failure to comply continues after the filing of the complaint until judgment is rendered." *Id.* §§ 31A-2-308(2), (8). Additionally, the Attorney General may impose criminal penalties. A manufacturer who "intentionally violates" S.B. 69 is "guilty of a class B misdemeanor," carrying a maximum criminal penalty of $10,000 for corporations or $5,000 for non-corporations. *Id.* §§ 31A-2-308(9)(a)–(b). UTAH CODE. ANN. § 31A-2-308(12) further provides that "[t]he enforcement penalties and procedures set forth in this section are not exclusive, but are cumulative of other rights and remedies the commissioner has pursuant to applicable law."

LEGAL STANDARD

The party seeking a preliminary injunction must establish: "(1) a likelihood of success on the merits; (2) a likelihood that the movant will suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the movant's favor; and (4) that the injunction is in the public interest." *RoDa Drilling Co. v. Siegal*, 552 F.3d 1203, 1208 (10th Cir. 2009) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). "When the government is the opposing party to a lawsuit, the third and fourth preliminary factors merge." *NetChoice, LLC v. Reyes*, 748 F. Supp. 3d 1105, 1131 (D. Utah Sept. 10, 2024) (citation omitted).

ARGUMENT

AbbVie satisfies all four preliminary injunction factors and is entitled to relief. ***First,*** AbbVie has a strong likelihood of success on the merits because S.B. 69 is unconstitutional in violation of the Supremacy, Takings and Due Process clauses. ***Second*****,** AbbVie will be irreparably harmed by enforcement of the law. ***Finally*****,** both the balance of the harms and the public interest favor AbbVie. This Court should grant AbbVie's motion for preliminary injunction.

I. ABBVIE IS LIKELY TO SUCCEED ON THE MERITS.

AbbVie is likely to show that S.B. 69 is unconstitutional and should be enjoined.

A. S.B. 69 Is Preempted.

Under the Constitution's Supremacy Clause, federal law is "the supreme law of the Land . . . any Thing in the Constitution or Laws of any State to the contrary notwithstanding." U.S. Const., art. VI. As a result, "Congress has the power to enact statutes that preempt state law." *US Airways, Inc. v. O'Donnell*, 627 F.3d 1318, 1324 (10th Cir. 2010). Federal law preempts S.B. 69 in two ways: ***First,*** it impermissibly intrudes on a field of federal regulation created and occupied by Congress. ***Second*****,** it conflicts with Congress's objectives in the 340B program by attempting to enforce an alternative interpretation of the 340B statute rejected by federal courts. As several courts have recognized, irreparable harm is presumed where a law is clearly preempted by federal law and the Court can and should grant preliminary injunctive relief based on likelihood of success on the merits alone. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992); *United States v. Alabama*, 691 F.3d 1269, 1301 (11th Cir. 2012). Governor Cox said it best when explaining his refusal to sign S.B. 69: the law "would require pharmaceutical manufacturers to ***extend federal*** 340B discounts to for-profit contract pharmacies," and

accordingly, concerns with a program "established by Congress . . . should be fixed at the federal level."[13]

Field Preemption. Because the supremacy of federal law is "essential to the existence and preservation of the government," the Supreme Court has long recognized that "[C]ongress should be able to exercise its constitutional powers, at its own discretion, without being subject to the control of state legislation." *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 330 (1819). Accordingly, state law is preempted whenever (1) Congress's "framework of regulation [is] 'so pervasive . . . that Congress left no room for the States to supplement it,'" or (2) there "is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *Bradshaw v. Am. Airlines, Inc.*, 123 F.4th 1168, 1173, 1178 (10th Cir. 2024) (holding that the federal standard of care for the operation of aircrafts "impliedly field preempts Oklahoma's 'common carrier' standard of care").

When Congress creates a "single integrated and all-embracing system" like the 340B program, it preempts the field. *Arizona*, 567 U.S. at 400 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 70, 74 (1941)). Section 340B erects a comprehensive regulatory scheme governing an exclusively federal program. Covered entities and contract pharmacies enjoy no pre-existing right to access manufacturers' drugs at deeply discounted prices; any access arises, if at all, from the Congressionally created 340B program. Indeed, every detail of the 340B program is determined by federal law, including which "covered entities" are eligible to participate and what consequences flow for participating manufacturers who fail to comply with statutory requirements.

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[13] *See* Letter from Gov. Spencer J. Cox to the Utah Legislature 5 (Mar. 27, 2025) ("Cox Letter") at 5 (emphasis added), https://tinyurl.com/2bkphyup.

Here, Utah seeks to re-define a federal term, 340B "covered entity," to include a 16th type: commercial contract pharmacies. And, unlike Medicaid—which expressly invites states to participate in administering a federal program—the 340B statute authorizes no ***state regulation*** of 340B pricing or entity eligibility to access manufacturers' drugs at 340B-discounted prices. In short, there is no room for states to interfere with the uniform federal scheme created by Congress or to impose additional state law obligations as conditions of participation in a purely federal healthcare program.

Yet, S.B. 69 seeks to do just that—impose new obligations on participants in a federal program that Congress has not authorized. The law's text confirms that it operates entirely within the federally occupied 340B field. The law prohibits pharmaceutical manufacturers from engaging in certain conduct with respect to the "340B drug discount program," "340B entit[ies]," and "340B drug[s]," terms the Legislature defined by reference to the federal 340B statute. *See* UTAH CODE ANN. §§ 31A-46-102(1)–(3). S.B. 69 could not exist but for the ***federal*** 340B statute. And it goes to the very heart of the federally occupied 340B field: It overrides the ***offer*** structure Congress established, eliminates manufacturers' federally permitted discretion, and dictates ***which*** entities must receive discounted drugs. *See Sanofi*, 58 F.4th at 706.

Conflict Preemption. S.B. 69 is also preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in creating the federal 340B program. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (quoting *Hines*, 312 U.S. at 67). ***First***, S.B. 69 conflicts with the 340B program's design. Congress "intentionally" omitted any obligation on manufacturers to transfer their drugs at 340B-discounted prices to contract pharmacies. *See Sanofi*, 58 F.4th at 704–05. This choice ensured that the 340B program—an ***adjunct condition*** to Medicare and Medicaid—would not eclipse the programs it

was designed to supplement. S.B. 69 overrides that design by actually re-defining the term "340B entity" to include commercial contract pharmacies and forcing manufacturers to provide 340B-priced drugs to a "pharmacy" and "any location authorized by a 340B entity to receive the drug." S.B. 69 § 1(2)(a)(i), (iii); UTAH CODE ANN. § 31A-46-102(3)(c).

In practice, that means that a contract pharmacy, defined as a ***new*** "340B entity" under Utah law, could place orders for drugs at the 340B price and direct their delivery to a third party. Although such a scenario is impossible under the federal scheme, failure to comply is punishable as a ***crime*** under Utah law. That Utah purports to merely further the ends of the 340B program is no defense: "[T]extual limitations upon a law's scope are no less a part of its 'purpose' than its substantive authorizations." *Rapanos v. United States*, 547 U.S. 715, 752 (2006). By requiring broad dissemination of 340B-priced drugs to contract pharmacies, S.B. 69 is designed to allow "covered entities" to "squeeze [more] revenue out of" the 340B program—even though Congress did not intend to "help [covered entities] maximize their 340B profits." *Sanofi*, 58 F.4th at 704.

Second, S.B. 69 contravenes HRSA's exclusive enforcement authority. "'Conflict is imminent' when 'two separate remedies are brought to bear on the same activity.'" *Crosby*, 530 U.S. at 380 (citation omitted) ("[T]he inconsistency of sanctions here undermines the congressional calibration of force."); *see also Arizona*, 567 U.S. at 408–09. "Congress can act so unequivocally as to make clear that it intends no regulation except its own," including by "regulat[ing] by one agency." *See Rice*, 331 U.S. at 234–36.

The Supreme Court confirmed that Congress granted HHS sole responsibility for administering the 340B program in *Astra*, 563 U.S. at 120. Congress delineated the specific enforcement tools and penalties available to the Secretary—audits, dispute resolution, and civil monetary penalties—*see* 42 U.S.C. §§ 256b(d)(l)(B)(v), (vi), (d)(3)—and placed enforcement

exclusively in HRSA's hands. *Id.* § 256b(d)(3)(A). Yet S.B. 69 authorizes both the Utah Insurance Commissioner and Attorney General to enforce criminal and civil penalties for alleged violations—remedies that directly conflict with the federal enforcement structure. *See* UTAH CODE ANN. § 31A-1-101 *et seq.*; UTAH CODE ANN. §§ 31A-2-201(4)(a), 31A-2-308. *See also Astra*, 563 U.S. at 120; *Morrisey*, 2024 WL 5147643, at *10 ("If private attempts to enforce the 340B Program go against 'what Congress contemplated when it "centralized enforcement in the government,"' . . . then so too would public attempts to enforce it." (quoting *Astra*, 563 U.S. at 119)); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 342–43, 349–50 (2001) (holding that where an agency has "a variety of enforcement options" to "make a measured response," state law remedies "inevitably conflict" with the agency's authority to police violations consistent with its judgment).[14]

What is more, the only avenue available to manufacturers to investigate and enforce a covered entity's suspected violation of the 340B statute's prohibition on diversion is through HRSA's mandatory federal audit system. Yet, manufacturers must demonstrate "reasonable cause" in order to obtain audit rights, and such "reasonable cause" requires data and other substantiating information be provided to the agency. 61 Fed. Reg. 65,406, 65,407 (Dec. 12, 1996) (providing that "audits are to be performed only when there is a reasonable cause to believe that there has been a violation" of the 340B statute). But S.B. 69 expressly forbids a manufacturer's ability to require "claims" or "utilization data" or indeed "any information" about its contracts with any third party. S.B. 69 § 1(2)(b)(ii). That functionally cuts off a manufacturers' ability to avail itself of the only defensive forum available to vindicate its rights, as held by the recent injunction

[14] *See* Exs. 10, 26, 27 (covered entities allege that manufacturers' policies result in overcharging—a purported violation that is governed exclusively by federal law).

issued by the West Virginia court. *Morrisey*, 2024 WL 5147643, at *6 (noting that "[b]y restricting a practice that the industry utilizes in order to take the first step toward accessing the 340B Program dispute resolution system, S.B. 325 creates an impermissible obstacle to executing the federal program.").

Utah cannot escape federal preemption by re-labeling S.B. 69 a "delivery regulation." The statute regulates ***pricing***, not "delivery." For one, the text makes clear it covers the "***acquisition*** . . . of a 340B drug," not simply delivery to a "location." S.B. 69 § 1(2)(a)(iii) (emphasis added). S.B. 69 penalizes manufacturers for refusing to attach 340B discounts to drugs shipped to for-profit pharmacies. AbbVie and other manufacturers gladly ***deliver*** unlimited quantities of drugs to for-profit pharmacies—they simply decline to do so at the 340B price. That is conduct federal law permits and S.B. 69 penalizes.[15] *See Morrisey*, 2024 WL 5147643, at *9 (manufacturers violate laws like S.B. 69 "not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering [their] drugs to those pharmacies"); *see also* Ex. 1, Scheidler Decl. ¶¶ 7a–c, 15f.

Whether the 340B statute has been found to be "silent about delivery," *see Sanofi*, 58 F.4th at 703, is beside the point. The "replenishment model"—unique to 340B—illustrates that S.B. 69 regulates not delivery, but ***price***. Under this model, pharmacies dispense drugs from general inventory—most of which was not purchased at 340B prices—and only ***later*** calculate how much they believe was dispensed to 340B-eligible patients. The covered entity then demands the

[15] *See* Ex. 14, July 1, 2024 Hr'g Tr., *Novartis Pharm. Corp. v. Brown*, No. 24-cv-01557 (D. Md.) at 34:11-22 (Ryan Dietrich and Howard Feldman, counsel for Defendant) (conceding that charging full price for a shipment of prescription drugs would violate Maryland's version of S.B. 69); *id.* at 40:21–41:1 (similar); *id.* at 55:15–17 (conceding that the state statute regulates manufacturer's pricing choices because "[t]he violation is they have to ***deliver at the 340B price***" (emphasis added)); *id.* at 56:19–20 (similar); *id.* at 57:24–58:2 (similar); *id.* at 58:22–25 (similar); *id.* at 74:22–23 (similar); *id.* at 75:11–13 (similar).

manufacturer "replenish" those units at the 340B price. *See* Ex. 13, Pedley Decl. ¶¶ 3–11; *see also* Ex. 1, Scheidler Decl. ¶¶ 8–12. Often, covered entities do not even place or approve these orders—pharmacies do. Ex. 1, Scheidler Decl. ¶ 10; *see also* 61 Fed. Reg. 43,549, 43,552 (August 23, 1996) (noting that "[b]ecause the covered entity will have no knowledge of the inventory levels of the pharmacy, it would be unrealistic to include a provision that the covered entity will order 340B drugs.").

This after-the-fact accounting mechanism ends with a manufacturer being required to transfer discounted drugs to commercial pharmacies to replenish their general inventory. That transfer of value is exactly what S.B. 69 compels. As the *Morrisey* court explained:

> Because the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy, the question is not about delivery of the drug. The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one.
>
> *Morrisey*, 2024 WL 5147643, at *8.

By contrast, a *bona fide* generally applicable delivery regulation—*e.g.*, requiring temperature-controlled trucks and inspections by the Utah DMV—would not intrude on any federally regulated field or conflict with federal law. But S.B. 69 does not regulate delivery; it compels manufacturers to offer drugs at ***340B prices*** under terms Congress never imposed.

Finally, the Eighth Circuit's decision to uphold a similar Arkansas law is legally distinguishable. *See PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024). ***First***, the Eighth Circuit had no occasion to address Takings or Due Process violations. ***Second***, the *McClain* court concluded that contract pharmacies acted as agents of covered entities. *Id.* at 1142–44. Agency requires action on the principal's behalf and under his control. *BancOklahoma Mortg. Corp. v. Cap. Title Co.*, 194 F.3d 1089, 1104 (10th Cir. 1999). And normally, as fiduciaries, agents must not commingle their property with their principal's. *See, e.g.*, *United States v. Riley*, 621 F.3d 312,

322–23 & 323 n.15 (3d Cir. 2010); *Hunter v. Shell Oil Co.*, 198 F.2d 485, 490 (5th Cir. 1952). The existence of agency relationships, even if present in Arkansas, is neither required by S.B. 69 nor supported by any evidence. Ex. 1, Scheidler Decl. ¶ 16.

Third, *McClain* emphasized that covered entities "maintain title" to 340B-discounted drugs held by contract pharmacies. 95 F.4th at 1144. But S.B. 69 imposes no such requirement, and the replenishment model ensures that the ***pharmacy***, not the covered entity, maintains title over 340B-priced drugs. *See* Ex. 1, Scheidler Decl. ¶¶ 12–13; Ex. 15 at 5–6, (June 2024 Article Sanofi and HRSA Suit) (covered entity spokesperson conceding that "the title to 340B drugs transfers to the contract pharmacy at the time it is taken into inventory"). Thus, as the *Morrisey* court warned, "it is likely that a drug manufacturer could both restrict distribution at the 340B price because of diversion concerns and be subject to sanction under [S.B. 69]." 2024 WL 5147643, at *11.

B. S.B. 69 Effects an Unconstitutional Taking of Private Property Without Just Compensation.

Even if not preempted, S.B. 69 effects an unconstitutional taking because it compels AbbVie and other manufacturers to sell their products at 340B-discounted prices, allowing contract pharmacies and covered entities to reap windfall profits. Ex. 16 at 8, 10, 15, N.C. (May 2024 N.C. Treasurer Report on Overcharges to State Employees); Ex. 17 at 338 (2024 NEJM Study on Hospital Prices for Physician-Administered Drugs).

The drugs that AbbVie manufactures are its property—protected by the Takings Clause like any other private property. That they are chattels, not land, is immaterial. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015). The most basic principle of takings law is that a government may not take property from private party A and give it to private party B. *See Kelo v. City of New London, Conn.*, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property

of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation"); *Hawaii Hous. Auth. v. Midkiff*, 467 U.S. 229, 245 (1984) ("A purely private taking could not withstand the scrutiny of the public use requirement[.]"). Such takings are always unconstitutional: "No amount of compensation" can cure them. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) ("[i]t is against all reason and justice" to allow government to "take[] property from A. and give[] it to B[.]").

S.B. 69 violates that principle. It forbids AbbVie from "restrict[ing]" or "prohibit[ing]," even "indirectly," the "acquisition" of AbbVie's ***own property*** by third parties, including private commercial pharmacies, "authorized" by "340B entit[ies]" regardless of location. *See* S.B. 69, § 1(2)(a)(iii). This is not a "public use" recognized in American law. *See Baker v. City of McKinney, Tex.*, 84 F.4th 378, 383 (5th Cir. 2023) (collecting recent Supreme Court cases). While the Supreme Court has sometimes permitted ***compensated*** transfers of property to private parties for carefully circumscribed reasons—such as curing a blight, *Berman v. Parker*, 348 U.S. 26, 31 (1954), or breaking a monopoly, *Midkiff*, 467 U.S. at 232–33—it has consistently forbidden takings that "confer[] a private benefit on a particular private party" or "to benefit a particular class of identifiable individuals." *Kelo*, 545 U.S. at 477–78 (quoting *Midkiff*, 467 U.S. at 245); *see also Fitch* Oral Argument, *supra*, at 28:21.52–28:33.04 (questioning what stops a covered entity from ordering "extra" discounted drugs "so that they can then sell those at the market price" and noting that "that's not for the 340[B program] at all. It's just so that the pharmacy can make more money."). That is what S.B. 69 does. If not enjoined, S.B. 69 would force AbbVie to transfer its property against its will to third parties and under conditions that it would have never agreed to.

Utah may argue that the voluntary participation doctrine bars this claim—that by voluntarily participating in the ***federal*** 340B program, AbbVie impliedly consented to ***state-***

imposed obligations. But that doctrine does not apply. While the Supreme Court has held that voluntarily accepting a government benefit in exchange for giving up property rights can extinguish a takings claim against the government who conferred the bargained-for benefit, *see Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984), that principle cannot justify separate state-imposed requirements where no state benefit is conferred. AbbVie voluntarily accepted ***federal*** 340B obligations as a condition of participating in the ***federal*** Medicare and Medicaid programs. S.B. 69 is a separate state law that imposes additional burdens with "no additional benefit." *See Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023); *see also Va. Hosp. & Healthcare Ass'n v. Roberts*, 671 F. Supp. 3d 633, 666 (E.D. Va. 2023) ("[T]hose *state law* . . . requirements have no bearing on whether providers' participation in Medicaid and Medicare are voluntary as a matter of *federal* law."); *Fitch* Oral Argument, *supra*, at 24:17.68–24:27.24.

In short, the Takings Clause exists "to bar [the] Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960). That is precisely what S.B. 69 does.

C. S.B. 69 Runs Afoul of the Due Process Clause.

The Due Process Clause of the Fifth Amendment guarantees that "[n]o person shall . . . be deprived of life, liberty, or property, without due process of law." U.S. Const., amend V. A law violates that fundamental guarantee when it is "so vague that it fails to give ordinary people fair notice of the conduct it punishes[.]" *Golicov v. Lynch*, 837 F.3d 1065, 1068 (10th Cir. 2016) (quoting *Johnson v. United States*, 576 U.S. 591, 595 (2015)). S.B. 69 is such a law. S.B. 69 prohibits a manufacturer's "interfer[ence] with . . . a contract between a pharmacy and a 340B entity." S.B. 69 § 1(2)(c)(i). A manufacturer is not a party to those contracts, those contracts are not publicly available, and indeed covered entities and contract pharmacies treat those contracts as

"proprietary" and are often fiercely resistant to disclosing their terms or otherwise making them available. In fact, S.B. 69 ***itself*** criminalizes any attempt to require disclosure of any "information about a 340B entity's contracts with a third-party as a condition for allowing the acquisition of a 340B drug." *Id.* § 1(2)(b)(ii). In other words, a manufacturer has no way of knowing the terms of those contracts—or how it might interfere with them—and is further prohibited from seeking that "information" as a condition of its offer. That fails even the basic notice required of criminal statutes under the Due Process clause. And moreover, the breadth of potentially incriminating conduct means S.B. 69 has the potential to chill a host of otherwise legal actions and speech. *See United States v. Guadreau*, 860 F.2d 357, 360 (10th Cir. 1988) (explaining a facial challenge is appropriate "when it threatens to chill constitutionally protected conduct").

Notably, S.B. 69 does not, itself, contain a scienter requirement that such interference be "intentional." (And Utah knows how to apply such an element, as it did in its tortious interference with economic relations jurisprudence. *Harvey v. Ute Indian Tribe of Uintah & Ouray Reservation*, 416 P.3d 401, 425 (Utah 2017)). Meaning, with respect to civil enforcement outside the scope of UTAH CODE ANN. § 31A-2-308(9), the lack of scienter in S.B. 69 means a manufacturer could interfere with a contract (whose terms they have no way of knowing) by accident. Such a scenario is incompatible Due Process. *See, e.g.*, *Papachristou v. City of Jacksonville*, 405 U.S. 156, 162–63 (1972) (citing *Screws v. United States*, 325 U.S. 91 (1945); *Johnson*, 576 U.S. at 595.

II. S.B. 69 WILL CAUSE ABBVIE IRREPARABLE HARM.

To obtain a preliminary injunction, the movant must show a likelihood of harm that is imminent and not compensable by damages. *RoDa Drilling*, 552 F.3d at 1210 (quotation marks and citation omitted). The harm must be "immediate"—likely to occur before the court rules on the merits. *Id.* Monetary damages "that cannot later be recovered . . . constitute[] irreparable

injury." *Chamber of Commerce of U.S. v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010); *see also Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764–65 (2021). AbbVie faces irreparable harm in two ways.

First, if S.B. 69 is enforced, AbbVie will be subject to ***state*** regulation—risking criminal and civil liability—merely for performing its federal obligations. Courts have repeatedly held that enforcement of a preempted law constitutes irreparable harm. *See Morales*, 504 U.S. at 381; *see also Occidental Petroleum Corp. v. Cities Serv. Co.*, 1982 WL 1376, at *8 (W.D. Okla. Dec. 20, 1982) (finding that enforcing a state law result in irreparable injury "because the Act is unconstitutional" and "denies Plaintiff rights" conferred by a federal statute); *Fish v. Kobach*, 840 F.3d 710, 754 (10th Cir. 2016).

Second, S.B. 69 mandates an ongoing unconstitutional taking of private property. The deprivation of constitutional rights constitutes irreparable harm for purposes of a preliminary injunction. *Awad v. Ziriax*, 670 F.3d 1111, 1131 (10th Cir. 2012) ("[W]hen an alleged constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary." (citation omitted)); *Burns v. Hickenlooper*, 2014 WL 3634834, at *2 (D. Colo. July 23, 2014) ("the deprivation of constitutional rights, for even minimal periods of time, constitutes irreparable harm."); Wright & Miller, Federal Practice and Procedure § 2948.1 (3d ed. 2024).

Courts have also found irreparable injury in the Takings context specifically, when allowing the taking to proceed would subject the property owner to "great" economic loss and could threaten "incalculable revenues." *Vaquería Tres Monjitas, Inc. v. Irizarry*, 587 F.3d 464, 485–86 (1st Cir. 2009) (affirming grant of preliminary injunction on takings claim); *Laclede Gas Co. v. St. Charles Cnty. Mo.*, 713 F.3d 413, 419–20 (8th Cir. 2013) (same); *cf. AAAG-California, LLC v. Kisana*, 439 F. Supp. 3d 1265, 1279 (D. Utah 2020) (noting, in breach of contract and

conversion case, that "the taking of property generally constitutes irreparable injury that will justify an injunction"). Every time S.B. 69 compels AbbVie to transfer discounted drugs to for-profit pharmacies, a taking occurs. Ex. 1, Scheidler Decl. ¶¶ 8–13; Ex. 13, Pedley Decl. ¶¶ 3–11. S.B. 69 makes no provision for covered entities to take or maintain title to those drugs; instead, it compels manufacturers to transfer discounted product directly to commercial pharmacies (or "any location"). *See* S.B. 69, § 1(2)(a)(i), (iv).

Once the 340B discount is provided and the drugs dispensed, there is no way to recover them—indeed presumably many have already been consumed by patients. Neither covered entities nor pharmacies can automatically refund AbbVie for unlawfully received discounts if the statute is later invalidated. Ex. 1, Scheidler Decl. ¶¶ 23–24. The revenue lost by S.B. 69's enactment undercuts AbbVie's business model and affects its ability to invest in the research and development of future life-saving products. *Id.* ¶¶ 23–26. Refusal to comply may expose AbbVie to civil and criminal penalties.

S.B. 69 presents a classic Hobson's choice: comply with an unconstitutional mandate or risk enforcement. *Id.* ¶¶ 23, 26. That dilemma is itself irreparable harm. *See NetChoice*, 748 F. Supp. 3d at 1130; *Mayor & City Council of Baltimore v. Azar*, 392 F. Supp. 3d 602, 618 (D. Md. 2019); *Bosarge v. Edney*, 669 F. Supp. 3d 598, 618 (S.D. Miss. 2023).

III. THE EQUITIES AND THE PUBLIC INTEREST FAVOR ABBVIE

Granting injunctive relief would not harm the State because it "does not have an interest in enforcing a law that is likely constitutionally infirm." *Edmondson*, 594 F.3d at 770–711); *see also Doe I v. Parish*, 2006 WL 8457272, at *5 (N.D. Okla. Sept. 14, 2006) ("The Tenth Circuit has held that the government is not harmed when it is enjoined from enforcing an unconstitutional statute."); *Bioganic Safety Brands, Inc. v. Ament*, 174 F. Supp. 2d 1168, 1179 (D. Colo. 2001).

Utah likewise cannot rely on imagined harm to its citizens, since there is no evidence that uninsured and needy patients—in Utah or anywhere else—benefit from the use of contract pharmacies. Exs. 3, 5–6, 15–25. Governor Cox refused to sign the bill in part over concerns that S.B. 69 "does not require cost savings to be passed onto patients and is not transparent in how cost savings are used." *See supra* n. 13. The State has no legitimate interest in enriching commercial pharmacies at the expense of manufacturers and patients. The public interest is better served by preventing unlawful takings and safeguarding the supremacy of federal law and due process. *Edmondson*, 594 F.3d at 770–711); *Awad*, 670 F.3d at 1132. Injunctive relief would ensure uniform federal standards and protect the balance Congress created in the 340B program.

CONCLUSION

The Court should grant AbbVie's motion for preliminary injunction.

REQUEST FOR ORAL ARGUMENT

Pursuant to DUCivR 7-1(g), AbbVie respectfully requests oral argument on this motion. Good cause exists because this motion raises significant constitutional questions under the Supremacy Clause and Takings Clause, and a hearing may assist the Court in evaluating the factual and legal complexities relevant to preliminary injunctive relief.

Dated: April 10, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Plaintiffs' Motion for a Preliminary Injunction was electronically filed with the Clerk of the Court via the Court's CM/ECF system, and we intend to attempt service on the parties listed below personally on April 10, 2025:

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